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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/905,709	08/05/1997	DAVID STERN	52876/JPW/JM	5754

7590 11/12/2003

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NEW YORK, NY 10036

EXAMINER	
LI, RUIXIANG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 11/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/905,709	STERN ET AL.	
	Examiner	Art Unit	
	Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 8, 9, 15-18, 36, 37 and 40-46 is/are pending in the application.
- 4a) Of the above claim(s) 40-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8, 9, 15-18, 36, 37 and 46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application, Amendments, and/or Claims

Applicants' amendment filed on August 11, 2003 has been entered in full. Claims 38 and 39 have been canceled. Claim 1 has been amended. Claims 1-4, 8, 9, 15-18, 36, 37, and 40-46 are pending. Claims 1-4, 8, 9, 15-18, 36, 37, and 46 are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Withdrawn Rejections/Objections

As a result of Applicants' amendment, all rejections/objections not reiterated herein have been withdrawn by the Examiner.

Priority

The subject matter defined in claims 1-4, 8, 9, 15-18, 36, 37, and 46 has been determined to have an effective filing date of August 5, 1997, which is the filing date of the Application 08/905,709. Application 08/592,070 (filed on January 26, 1996) fails to provide adequate support under 35 USC §112 for the instantly claimed invention.

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Applicants argue that Applications 08/592,070 provides adequate support under 35 USC §112 for the subject matter of claims 1-4, 8, 9, 15-18, 36, 37, and 46, as amended. This has been fully considered but is not deemed to be persuasive for the following reasons. While disclosing (i) a method for inhibiting interaction of an amyloid- β peptide with a receptor for advanced glycation end product (RAGE) on the surface of a cell which comprises contacting the cell with an agent capable of inhibiting interaction of the amyloid- β peptide with the RAGE (top of page 11), (ii) the use of soluble RAGE as the agent in the method (bottom of page 11), and (iii) the RAGE NH₂-terminal sequence (Table 1, page 29), the applications 08/592,070 fails to **contemplate and enable** the claimed invention, as amended. The specification of application 08/592,070 merely asserts a method for treating a subject with a condition associated with interaction of an amyloid- β peptide with an RAGE on a cell, which comprises administering to the subject an agent capable of inhibiting interaction of the amyloid- β peptide with the RAGE (bottom of page 13). The long list of conditions includes diabetes, Alzheimer's disease, senility, renal failure, hyperlipidemic atherosclerosis, neuronal cytotoxicity, Down's syndrome, dementia associated with head trauma, amyotrophic lateral sclerosis, multiple sclerosis or neuronal degeneration (bottom of page 13). There is no demonstration that the interaction of amyloid- β peptide with the RAGE is actively involved in each of these diseases, including hyperlipidemic atherosclerosis; there is no disclosure of treatment of a condition, including hyperlipidemic atherosclerosis, with the extracellular domains of RAGE or sRAGE; there is no sufficient guidance or working examples provided to teach an artisan how to treat a condition, including hyperlipidemic atherosclerosis with a method comprising administering sRAGE. There was no

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sufficient teaching in the art regarding the treatment of hyperlipidemic atherosclerosis with sRAGE at the time the application 08/592,070 was filed. Therefore, the application of 08/592,070 fails to contemplate and enable the claimed invention.

Claim Rejections Under 35 U. S. C. § 112, 2nd Paragraph

Claims 1-4, 8, 9, 15-18, 36, 37, and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because it recites “the extracellular domain of soluble receptor for advanced glycation endproduct (sRAGE)”. The specification of 08/905,709 defines sRAGE as “the extracellular portion of RAGE” (page 31, lines 27-28), whereas the specification of 08592070 defines sRAGE” as the extracellular domain of RAGE (page 30, line 15). From these definitions, it is clear that the term sRAGE itself is the extracellular domain. Thus, recitation of “the extracellular domain of soluble receptor for advanced glycation endproduct (sRAGE)” in the claim is confusing. In addition, there is no sequence identifier (SEQ ID NO) provided for the specific extracellular domain recited in the claim, it is unclear which extracellular domain (sRAGE) or which RAGE is referred to, rendering the claim indefinite. It is suggested that a sequence identifier be provided for RAGE, sRAGE, and AGE. Claims 2-4, 8, 9, 15-18, 36, 37, and 46 depend from claim 1.

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Claim Rejections Under 35 U. S. C. § 102(e)

The rejection of claims 1-4, 8, 9, 15-18, 36, 37, and 46 under 35 U.S.C. § 102 (e), as set forth at pages 5-7 in Paper No. 21 & 24 remains.

Applicants argue that the claimed invention is entitled to a priority date of January 26, 1996. This has been fully considered but is not deemed to be persuasive because application 08/592,070, filed on January 26, 1996, fails to contemplate and enable the instantly claimed invention as a whole, as noted above.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li
Examiner
November 4, 2003


GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600